Patent
147117-100002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

BOARD OF PATENT APPEALS AND INTERFERENCES

Application No.: 10/014,977	**Confirmation No. 3321**
Applicant: Michael Webber	
Filed: December 10, 2001	
TC/AU: 3736	
Examiner: R. Nasser	
Docket No. 147117-100002	
Customer No. 34026	

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF SUBSTITUTE APPEAL BRIEF

In response to the Office Action of May 26, 2006, Applicants hereby enclose for filing a substitute Appeal Brief for the above referenced application. Applicants have already paid the fee for filing an appeal brief, however, if any additional fee is required please charge Jones Day's Deposit Account No. **50-2468**.

CERTIFICATE OF MAILING
(37 C.F.R. §1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as First Class Mail in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Fay Lum-Lee
Name of Person Mailing Paper

Fay Lum-Lee
Signature of Person Mailing Paper

June 7, 2006
Date of Deposit

LAI-2246894v1

Respectfully submitted,

JONES DAY

Dated: June 7, 2006

By: _____
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APPEAL BRIEF PURSUANT TO 37 CFR § 41.37(c)

Real Party In Interest

The real party in interest is Pranalytica, Inc., located at 1101 Colorado Boulevard in Santa Monica, California. An assignment by Appellant Dr. Michael Webber to Pranalytica of this application was recorded on April 4, 2002 (Reel/Frame: 012771/0169).

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(37 C.F.R. §1.8a)

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Related Appeals and Interferences

Neither Appellant nor Appellant's assignee or attorney are aware of another Appeal or Interference that will affect or have a bearing on the Board's decision of this Appeal.

Status of Claims

Claims 1, 4-6, 8-11, 13, 14, 17-22, 24-26, 29-34, 36, 37 and 39-42 are rejected. No claims are allowed.

Status of Amendments

No Amendment has been filed subsequent to the Final Rejection in this case.

Summary of claimed subject matter

There are four independent claims on appeal, claims 1, 11, 20 and 32. A summary of the claimed subject matter for each of these claims is set out below:

Claim 1

Breath is expired through an analysis chamber 11, having an inlet 13 and outlet 15 (Figure 3, page 12, paragraph 34, lines 17-18). The concentration of a first component of the breath is monitored by measuring the light energy absorbed by the first component of breath in order to determine when alveolar breath is present in the analysis chamber (Figure 3, light detector 25 and logic processor 27, page 13, paragraphs 35 and 36, lines 3-21). Based on the concentration of the first component in the immediately previous expired breath indicating alveolar breath, a concentration spectroscopic measurement of a second component of breath is made (Figure 3, spectrometer 19, page 14, paragraph 37, lines 9-20).

Claim 11

This claim has all of the features of claim 1 which are repeated below:

Breath is expired through an analysis chamber 11, having an inlet 13 and outlet 15 (Figure 3, page 12, paragraph 34, lines 17-18). The concentration of a first component of the breath is monitored by measuring the light energy absorbed by the first component of breath in order to determine when alveolar breath is present in the analysis chamber (Figure 3, light detector 25 and logic processor 27, page 13, paragraphs 35 and 36, lines 3-21). Based on the concentration of the first component in the immediately previous expired breath indicating alveolar breath, a concentration spectroscopic measurement of a second component of breath is made (Figure 3, spectrometer 19, page 14, paragraph 37, lines 9-20).

In addition, claim 11 includes the following feature:

Comparing each measured concentration of the first compound of breath to a threshold concentration to determine when alveolar breath is present in the analysis chamber 11 (Figure 2, page 9, paragraph 26, lines 15-21; paragraph 32, page 11, line 18-page 12, line 7).

Claim 20

Claim 20 has all of the features of claim 1 which are repeated below:

Breath is expired through an analysis chamber 11, having an inlet 13 and outlet 15 (Figure 3, page 12, paragraph 34, lines 17-18). The concentration of a first component of the breath is monitored by measuring the light energy absorbed by the first component of breath in order to determine when alveolar breath is present in the analysis chamber (Figure 3, light detector 25 and logic processor 27, page 13, paragraphs 35 and 36, lines 3-21). Based on the concentration of the first component in the immediately previous expired breath indicating alveolar breath, a concentration spectroscopic measurement of a second component of breath is made (Figure 3, spectrometer 19, page 14, paragraph 37, lines 9-20).

In addition, claim 20 includes two additional features:

Passing light through the breath in the analysis chamber 11, the light having a wavelength corresponding to a first absorption feature of the first compound of breath (Figure 3, light source 21, wavelength selector 23 and light detector 25, paragraph 34, page 12, line 19-page 13, line 2).

Multiplexing the light at first and second wavelengths prior to entering the analysis chamber (Figure 6, multiplexing unit 49; paragraph 42, page 16, lines 18-20).

Claim 32

Claim 32 contains all of the features of claim 20 which are repeated below:

Breath is expired through an analysis chamber 11, having an inlet 13 and outlet 15 (Figure 3, page 12, paragraph 34, lines 17-18). The concentration of a first component of the breath is monitored by measuring the light energy absorbed by the first component of breath in order to determine when alveolar breath is present in the analysis chamber (Figure 3, light detector 25 and logic processor 27, page 13, paragraphs 35 and 36, lines 3-21). Based on the concentration of the first component in the immediately previous expired breath indicating alveolar breath, a concentration spectroscopic measurement of a second component of breath is made (Figure 3, spectrometer 19, page 14, paragraph 37, lines 9-20).

In addition, claim 20 includes two additional features:

Passing light through the breath in the analysis chamber 11, the light having a wavelength corresponding to a first absorption feature of the first compound of breath (Figure 3, light source 21, wavelength selector 23 and light detector 25, paragraph 34, page 12, line 19-page 13, line 2).

Multiplexing the light at first and second wavelengths prior to entering the analysis chamber (Figure 6, multiplexing unit 49; paragraph 42, page 16, lines 18-20).

In addition, claim 32 includes the following feature:

Comparing each calculated spectroscopic concentration of the first component to determine when alveolar breath is present in the analysis chamber 11 (Figure 3, first spectrometer 17, paragraph 34, page 12, line 19-page 13, line 8).

Grounds of rejection on appeal

All of the claims were rejected on 35 U.S.C. § 103.

(1) Claims 1, 4-6, 8, 10, 11, 13, 14, 17 and 19 were rejected based on a combination of three patents, Kiefer (3,830,630), in view of Forrester (5,376,555) and Phillipps (4,582,068); (2) Claims 1, 4-6, 8,, 9, 11, 13, 14, 17 and 18 were rejected based on a combination of five patents, Gustafsson (6,038,913), in view of Kiefer, Forrester, Phillipps and Culver (5,445,160); (3) Claims 20, 21, 22, 24-26, 29, 31-34, 36, 37, 39, 40 and 42 were rejected based on a combination of four patents, Kiefer, Forrester, Phillipps, and Gratton; and (4) claims 20, 21, 22, 24-26, 30, 32-34, 36, 37, 39, 41 and 42 were rejected based on a combination of five patents, Gustafsson (6,038,913), Kiefer, Forrester, Culver and Gratton.

ARGUMENT

As held by the Federal Circuit in the case of *In re Geiger*, 2 U.S.P.Q.2d 1277, 1278 (1987):

> Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination. *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). We are convinced that the latter are not present here.

A. Claims 1, 4-6, 8, 10, 11, 13, 14, 17 and 19

These claims were rejected based on the patents Kiefer, Forrester and Phillipps. The Examiner's May 19, 2005 Final Office Action, at page 2, admits that the "combination [of Kiefer

and Forrester] does not base the trigger threshold on previous measurements. Phillipps et al. is a breath monitoring device where a threshold is updated based only upon the immediately previous measurement, to tune the device to the particular patient."

All of Applicant's claims above recite the measurement of two components of breath. Phillipps does not measure two components of breath. Indeed, it does not measure any component of breath. Rather, Phillipps determines changes in a patient's thoracic volume, and then filters a heart rate signal (col.. 2, lines 45-51). Thus neither Phillipps, nor any of the three cited references, alone or together, teach "triggering at least one concentration spectroscopic measurement for a second component of breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately expired breath" as recited in call of the claims above. It is respectfully submitted that the Examiner has engaged in impermissible hindsight in looking for references that collectively disclose various aspects of the claimed invention, without citing to any teaching in the patents as to why one would combine them.

The Examiner says that it would be obvious to update the threshold of the combination of Kiefer and Forrester in view of Phillipps (pages 2-3 of Final Rejection). But, there is no suggestion to make such a combination of the Kiefer, Forrester and Culver/or Phillips references. Indeed, the references teach against such combination "to update the threshold."

In Kiefer, the threshold is <u>fixed</u> at 4.5%:

> filament 17 is **purposely designed** so that a 4-1/2% CO_2 content in the breath sample causes filament 17 to unbalance the bridge of which it is a part . . . . (col. 4, l. 13-15)

Thus, there is no teaching in Kiefer that the device "purposely designed" to have a fixed, static threshold of 4.5 could be modified to measure alveolar breath "based on the concentration of the first component in a previously expired breath" as disclosed and claimed by Appellant.

If the threshold were to be changed in Kiefer based on previously expelled breath, filament branch 17, specifically designed for a 4.5 threshold, would have to be removed and replaced by another filament in the electrical balance bridge capacitor between patient breaths. Stated differently, the suggested combination would render Kiefer inoperative.

Similarly, Forrester discloses a "**predetermined** threshold" (col. 5, l. 51). Forrester uses thermopile infrared detectors for measuring gas analysis, but notes that the filament sensor of Kiefer could also be used (col. 6, l. 19-23). So again, Forrester teaches a fixed predetermined threshold, and contains no suggestion that it be combined with Phillips.

B. Claims 1, 4-6, 8, 9, 11, 13, 14, 17 and 18

Here the principal reference is Gustafsson. The May 19, 2005 Final Rejection, at page 3, admits that this reference does not teach a method ensuring that only alveolar breath components are measured.

But there are further deficiencies in the Gustafsson reference when applied to applicant's claims. Gustafsson does not measure two breath components of breath, it measure a single component. Moreover, it does not teach "triggering at least one concentration spectroscopic measurement for a second component of breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately expired breath."

As pointed out earlier, this feature is not found in the Kiefer, Forrester or Phillipps references either. This brings us to Culver, the fifth patent relied on by the Examiner to support

his obviousness rejection. First, in an Interview Summary dated April 13, 2005, the Examiner admitted that the amendment (subsequently entered and appearing in all of the claims above) would distinguish Culver:

> Applicant proposed an amendment to claims to limit the rigerring [sic] step to be based on only the immediately previous measurement. Applicant noted that Culver's measurement was based on 4 predeeding [sic] measurements (see columns 5 and 6). The examiner agreed and noted that such a limitation would define over the rejection based on Culver, but that an update search was necessary before deciding on ultimate allowability.

Culver does not measure two components of breath; it simply detects whether a patient has stopped breathing (col. 3, lines 55-62). Accordingly, this reference, as is true of the other four patents relied on, does not teach the limitation found in all of the claims above that "triggering at least one concentration spectroscopic measurement for a second component of breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately expired breath."

C. Claims 20, 21, 22, 24-26, 29, 31-34, 36, 37, 39, 40 and 42

These claims have all of the limitations of independent claims 1 and 11 discussed above, as well as the limitations of using a multiplexer an passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath. Further,, as to claims 32-34, 36, 37, 39, 40 and 42, the feature of comparing calculated spectroscopic concentrations is also present. Here, the Examiner again relies on the combination of Kiefer, Forrester and Phillipps, discussed above, plus Gratton, directed tot measuring substances through tissue (col. 2, lines 58-60). While Gratton shows a multiplexer, it has nothing to do with the measurement of breath components. And none of the four patents disclosed "triggering at least one concentration spectroscopic measurement for a

second component of breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately expired breath" that is present in all of these claims. And we find no teaching of spectroscopic calculation in any of the cited references.

D. Claims 20, 21, 22, 24-26, 29, 30, 32-34, 36, 37, 39, 41 and 42

Here, the Examiner relies on Keifer and Forrester (a combination that admittedly "does not teach a method ensuring that only alveolar breath components are measured) plus Gustafsson (that does not measure two breath components) plus Culver (admitted distinguished by the language of "triggering at least one concentration spectroscopic measurement for a second component of breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately expired breath" present in all of these claims) plus Gratton (that does not measure breath at all). Even if all of the patents directed to dissimilar subject matter were properly combined, and we submit they are not, they still do not show the feature of "triggering at least one concentration spectroscopic measurement for a second component of breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately expired breath."

It is respectfully submitted that the Examiner has improperly engaged in impermissible hindsight by selecting various features from a number of patents in different fields.

Respectfully submitted

JONES DAY

Date: June 7, 2006

By _____
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CLAIMS APPENDIX

1. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

continuously monitoring a concentration of a first component of the breath by measuring the light energy absorbed by the first component as the breath is expired through the analysis chamber to determine when alveolar breath is in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath.

4. The method of claim 1, wherein triggering the at least one concentration measurement of the second component of the breath includes triggering the at least one concentration measurement when the concentration of the first component crosses a threshold concentration.

5. The method of claim 4, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

6. The method of claim 4, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

8. The method of claim 1, wherein the first component is carbon dioxide, oxygen, or water vapor.

9. The method of claim 1, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

10. The method of claim 1, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

11. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

continuously measuring a concentration of a first component of the breath expired through the analysis chamber by means of measuring the light energy absorbed by the first component;

comparing each measured concentration of the first component to a threshold concentration to determine when alveolar breath is in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of a second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath.

13. The method of claim 11, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

14. The method of claim 11, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

17. The method of claim 11, wherein the first component is carbon dioxide, oxygen, or water vapor.

18. The method of claim 11, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

19. The method of claim 11, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

20. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath;

continuously measuring absorption of the light at the first wavelength by the first component to determine when alveolar breath is present in the analysis chamber; and

triggering at least one concentration spectroscopic measurement of the second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath

wherein the light at the first wavelength and the light at the second wavelength are multiplexed prior to entering the analysis chamber.

21. The method of claim 20, wherein the light further comprises a second wavelength corresponding to a second absorption feature of the second component.

22. The method of claim 21, wherein the light at the first wavelength and the light at the second wavelength follow substantially similar paths in the analysis chamber.

24. The method of claim 20, wherein triggering the at least one concentration measurement of the second component of the alveolar breath in the analysis chamber includes triggering the at least one concentration measurement when the concentration of the first component crosses a threshold concentration.

25. The method of claim 24, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

26. The method of claim 24, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

29. The method of claim 20, wherein the first component is carbon dioxide, oxygen, or water vapor.

30. The method of claim 20, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

31. The method of claim 20, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

32. A method of analyzing alveolar breath comprising:

expiring breath through an analysis chamber;

passing light through the breath in the analysis chamber, the light comprising a first wavelength corresponding to a first absorption feature of a first component of the breath;

continuously calculating a concentration of the first component of the breath by monitoring absorption of the light at the first wavelength by the first component;

comparing each calculated spectroscopic concentration of the first component to determine when alveolar breath is present in the analysis chamber; and

triggering at least one concentration measurement of the second component of the breath once the alveolar breath is in the analysis chamber, based on the concentration of the first component in only the immediately previous expired breath

wherein the light at the first wavelength and the light at the second wavelength are multiplexed prior to entering the analysis chamber.

33. The method of claim 32, wherein the light further comprises a second wavelength corresponding to a second absorption feature of the second component.

34. The method of claim 33, wherein the light at the first wavelength and the light at the second wavelength follow substantially similar paths in the analysis chamber.

36. The method of claim 32, wherein the threshold concentration is at least 3.5% relative concentration of the first component.

37. The method of claim 32, wherein the threshold concentration is at least 4.5% relative concentration of the first component.

39. The method of claim 32, wherein triggering the at least one concentration measurement of the second component of the alveolar breath in the analysis chamber includes triggering at least one spectroscopic measurement of the second component.

40. The method of claim 32, wherein the first component is carbon dioxide, oxygen, or water vapor.

41. The method of claim 32, wherein the second component is ammonia, nitric oxide, or a carbon dioxide isotope.

42. The method of claim 32, wherein the second component is an element selected from one of the following chemical groups: alcohols, alkanes, and ketones.

EVIDENCE APPENDIX

A copy of the Interview Summary of April 13, 2005 entered by the Examiner is attached. Copies of the six patents relied on by the Examiner in his obviousness rejection (Kiefer, Forrester, Phillipps, Gratton, Culver and Gustafsson) are also attached.

Interview Summary	Application No.	Applicant(s)	
	10/014,977	WEBBER, MICHAEL EVAN	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Robert L. Nasser*. (3)_____.

(2) *Mr. Coe Bloomberg*. (4)_____.

Date of Interview: *13 April 2005*.

Type: a)☐ Telephonic b)☐ Video Conference
c)☒ Personal [copy given to: 1)☐ applicant 2)☒ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☒ No.
If Yes, brief description: _____.

Claim(s) discussed: *all*.

Identification of prior art discussed: *Culver 5445160*.

Agreement with respect to the claims f)☒ was reached. g)☐ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *Applicant proposed an amendment to the claims to limit the rigerring step to be based on only the immediately previous measurement. Applicant noted that Culver's measurement was based on 4 predeeding measurements (see columns 5 and 6). The examiner agreed and noted that such a limitation would define over the rejection based on Culver, but that an update search was necessary before deciding on ultimate allowability.*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Robert L Nasser

Examiner's signature, if required